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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 04/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,276

Applicant(s)

PRAYAGA ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 18-34, 36, 37 and 39-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 35 and 38 is/are rejected.
- 7) ☒ Claim(s) 15-17, 35 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, antibodies, and species election of SEQ ID NO:5 in Paper No. 12 is acknowledged. The restriction requirement of paper no. 10 is made final. Claims 1-48 are pending in this application. Claims 1-14, 18-34, 36, 37, and 39-48 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Objections

2. Claims 15-17, 35, and 38 are objected to because of the following informalities as depending from a non-elected claim.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 15 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Because the claim does not require that the antibody be isolated, it encompasses products of nature.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 15, 16, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., *Oncogene*, 1991, vol. 6, no. 6, pp. 1057-1061, or Park et al., *Oncogene*, 1997, vol. 14, pp. 553-542, in view of Harlow et al., Antibodies, 1988.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Chen et al. teaches human eek. Chen et al. provided only a partial sequence. However, the complete sequence of eek is identical to Applicant's SEQ ID NO: 5, as is stated by Applicant on p. 10, lines 35-39. Park et al. teach mouse eek, which is 95.6% identical to human eek, and thus meets the limitation of being less than 15% different from SEQ ID NO: 5. Neither Chen nor Park teach antibodies. Harlow et al. teaches on many different uses for antibodies including, for example, cell staining (p. 361), immunoprecipitation, (p. 423), immunoblotting (p. 473), immunoaffinity purification (p. 513), and immunoassays (p. 555). Harlow et al. further teaches monoclonal antibodies, as claimed in instant claim 16, on p. 148 and teaches on p. 541 that these antibodies have advantages over polyclonal antibodies. That antibodies may be stored in pharmaceutically acceptable carriers, as claimed in claims 35 and 38, is taught on p. 287. Harlow et al. fails to teach antibodies to the protein of Chen et al. or Park et al. However, it would be *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Chen et al. or Park et al. with those of Harlow et al. to arrive at the claimed invention. One of ordinary

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skill would be motivated to do so because Harlow et al. teaches many uses for such antibodies, as well as means of making them. Thus one of ordinary skill would expect to be able to generate such antibodies and to use them for the study of the protein, as taught by Harlow et al.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. or Park et al. in view of Harlow et al. as applied to claims 15, 16, 35, and 38 above, and further in view of Morrison et al., in *Advances in Immunology*, vol. 44, 1989. Chen et al., Park et al., and Harlow et al. teach as set forth above but fail to teach humanized antibodies. Such antibodies are taught by Morrison et al. on pp. 79-82. Morrison et al. fails to teach antibodies to instant SEQ ID NO: 5. However, it would be obvious to one of ordinary skill in the art to combine the teachings of Morrison et al. with those of Chen et al. or Park et al. and Harlow et al. to produce humanized antibodies. One of ordinary skill would have been motivated to do so because Morrison et al. teaches that such antibodies avoid deleterious immune responses. Thus one of ordinary skill would expect such antibodies to be useful.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.
Patent Examiner

April 20, 2003